

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

COSMO TECHNOLOGIES LIMITED,	:
VALEANT PHARMACEUTICALS	:
INTERNATIONAL, and VALEANT	:
PHARMACEUTICALS LUXEMBOURG	:
S.À R.L.,	:
Plaintiffs,	:
v.	:
LUPIN LTD. and LUPIN	:
PHARMACEUTICALS, INC.,	:
Defendants.	:
COSMO TECHNOLOGIES LIMITED,	:
VALEANT PHARMACEUTICALS	:
INTERNATIONAL, and VALEANT	:
PHARMACEUTICALS LUXEMBOURG	:
S.À R.L.,	:
Plaintiffs,	:
v.	:
MYLAN PHARMACEUTICALS INC.,	:
Defendant.	:

Jack B. Blumenfeld and Maryellen Noreika, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE
Melanie R. Rupert, David M. Conca, and Nicholas A. Tymoczko, PAUL HASTINGS LLP, New York, NY

Attorneys for Plaintiffs.

Daniel B. Rath and James S. Green Jr., LANDIS RATH & COBB LLP, Wilmington, DE
William R. Zimmerman, Andrew E. Morrell, and Andrea L. Cheek, KNOBBE, MARTENS, OLSON & BEAR, LLP, Washington, DC
Carol Pitzel Cruz, KNOBBE, MARTENS, OLSON & BEAR, LLP, Seattle, WA
Sheila N. Swaroop and Stephanie Johnson, KNOBBE, MARTENS, OLSON & BEAR, LLP, Irvine, CA

Loni L. Morrow, KNOBBE, MARTENS, OLSON & BEAR, LLP, San Diego, CA

Attorneys for Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc.

James M. Lennon and Robert M. Vrana, YOUNG CONAWAY STARGATT & TAYLOR, LLP, Wilmington, DE

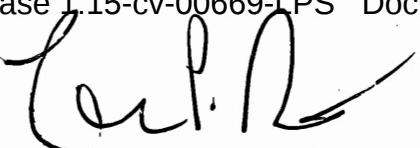
Deepro R. Mukerjee, Lance Soderstrom, and Stephanie M. Roberts, ALSTON & BIRD LLP, New York, NY

Joseph M. Janusz, ALSTON & BIRD LLP, Charlotte, NC

Attorneys for Defendant Mylan Pharmaceuticals, Inc.

MEMORANDUM OPINION

March 15, 2017
Wilmington, Delaware


STARK, U.S. District Judge:

Plaintiffs Cosmo Technologies Limited, Valeant Pharmaceuticals International, and Valeant Pharmaceuticals Luxembourg S.à r.l. (collectively, "Cosmo") filed suit against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") and separately, Defendant Mylan Pharmaceuticals Inc. ("Mylan"), alleging infringement of U.S. Patent Nos. 7,410,651; RE 43,799; 8,784,888; and 9,320,716.¹ The patents describe and claim controlled-release pharmaceutical compositions containing budesonide, which are used to treat ulcerative colitis.

Presently before the Court is the issue of claim construction. The Court previously construed terms of the patents in suit in related litigation. *See Cosmo Techs. Ltd. v. Actavis Labs. FL, Inc.*, 2016 WL 4697953 (D. Del. Sept. 7, 2016). The parties submitted technology tutorials (*see* C.A. No. 15-669-LPS D.I. 91, 95;² C.A. No. 16-152-LPS D.I. 39) and briefs (*see* D.I. 92, 96, 102, 105; C.A. No. 16-152-LPS D.I. 40, 56). The parties elected to forgo a claim construction hearing. (*See* D.I. 113)

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude."

¹Cosmo also asserts U.S. Patent 8,293,273 against Mylan. (*See* C.A. No. 16-152-LPS D.I. 43 at ¶ 5)

²Unless otherwise noted, citations to the record will be to C.A. No. 15-669-LPS.

Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted).

“[T]here is no magic formula or catechism for conducting claim construction.” *Id.* at 1324.

Instead, the court is free to attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.*

“[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1312-13 (internal citations and quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). The patent specification “is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” the context of the surrounding words of the claim also must be considered.

Phillips, 415 F.3d at 1314. Furthermore, “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . .” *Id.* (internal citation omitted).

It is likewise true that “[d]ifferences among claims can also be a useful guide . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15 (internal citation omitted). This “presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one

party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316. It bears emphasis that “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

In addition to the specification, a court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370 (1996). The prosecution history, which is “intrinsic evidence,” “consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

In some cases, “the district court will need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period.” *Teva*, 135 S. Ct. at

841. Extrinsic evidence “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries “endeavor to collect the accepted meanings of terms used in various fields of science and technology.” *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.* Nonetheless, courts must not lose sight of the fact that “expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.* Overall, while extrinsic evidence “may be useful” to the court, it is “less reliable” than intrinsic evidence, and its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GmbH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007)

(quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF DISPUTED TERMS

A. Lipophilic, Amphiphilic, and Hydrophilic

“lipophilic”³

Cosmo “having an affinity for lipids and a poor affinity towards aqueous fluids”
Lupin “having an affinity for lipids and a poor affinity for aqueous fluids and not characterized as hydrophilic or amphiphilic”
Court “having an affinity for lipids and a poor affinity towards aqueous fluids”

“amphiphilic”⁴

Cosmo “having an affinity for lipids and an affinity for water”
Lupin “having an affinity for lipids and an affinity for water and not characterized as lipophilic or hydrophilic”
Court “having an affinity for lipids and an affinity for water”

³This term appears in claims 1, 3, 4, 6, 8, and 9 of the ’651 patent; claims 1, 3, 4, and 6 of the ’799 patent; claims 1, 9, 10, 19, 20, and 22 of the ’716 patent; and claims 1, 5, and 9 of the ’888 patent.

⁴This term appears in claims 1, 2, 5, 8, and 9 of the ’651 patent; claims 1, 2, and 5 of the ’799 patent; claims 6, 7, 8, 12, 17, 18, and 22 of the ’716 patent; and claims 1 and 7 of the ’888 patent.

“hydrophilic”⁵

Cosmo
“having an affinity for water”
Lupin
“having an affinity for water and a poor affinity for lipids and not characterized as lipophilic or amphiphilic”
Court
“having an affinity for water”

The Court previously construed the terms lipophilic, amphiphilic, and hydrophilic in the context of matrices, *e.g.*, “amphiphilic matrix.” *See Cosmo*, 2016 WL 4697953, at *5-6. Lupin requests that the Court clarify that these three terms are distinct, such that, for example, a component that is amphiphilic cannot also be hydrophilic or lipophilic.

The parties’ briefing demonstrates that there is no dispute that the terms are distinct. (*See* D.I. 102 at 2; D.I. 105 at 4; C.A. No. 16-152 D.I. 40 at 5, 56 at 1) As is well understood in the art, a component will have an affinity for water *or* have an affinity for lipids *or* have an affinity for both. *See* ’651 patent col. 3 ll. 47-56, col. 4 ll. 21-36 (listing compounds that fall into each category). The patents and prosecution history indicate that the patentee used these terms consistent with the ordinary meaning ascribed to them. (*See, e.g.*, D.I. 83 Ex. 8 at 9-10, Ex. 30 at 3)

The Court agrees with Lupin that a person of ordinary skill in the art would understand these terms to be mutually exclusive as used in the context of the patents-in-suit. In the Court’s view, the constructions it previously adopted already account for the mutual exclusivity of these

⁵This term appears in claims 1, 7, and 9 of the ’651 patent; claims 1 and 7 of the ’799 patent; claims 1, 3-5, 12, 14-16, and 22 of the ’716 patent; and claims 1, 2, 4, 6, and 8 of the ’888 patent.

terms. Hence, the Court is not persuaded that any modification of its previous constructions is necessary. Nor is the Court persuaded that the construction of “hydrophilic” needs to include that the component has a poor affinity for lipids. (*See, e.g.*, D.I. 96 Ex. 5) (defining “hydrophilic” as “[h]aving an affinity for . . . water”) By virtue of the terms being mutually exclusive, it is already clear that a hydrophilic component must have a poor affinity for lipids, as a component with an affinity for water *and* lipids is amphiphilic.

Accordingly, the Court will adopt Cosmo’s proposed constructions.

B. Matrix terms

“amphiphilic matrix”⁶

Cosmo

“a matrix containing amphiphilic substances, and as a result having an affinity for lipids and an affinity for water”

Lupin

“a matrix containing amphiphilic substances, and as a result having an affinity for lipids and an affinity for water, and not characterized as lipophilic or hydrophilic”

Court

“a matrix containing amphiphilic substances, and as a result having an affinity for lipids and an affinity for water”

“a lipophilic matrix consisting of lipophilic compounds”⁷

Cosmo

“a matrix having an affinity for lipids and a poor affinity towards aqueous fluids”

⁶This term appears in claims 1 and 2 of the ’651 patent and claims 1, 2, and 5 of the ’799 patent.

⁷This term appears in claim 1 of the ’651 patent and claim 1 of the ’799 patent.

Lupin

“a matrix containing only lipophilic compounds and as a result having an affinity for lipids and a poor affinity towards aqueous fluids as a whole, and not characterized as hydrophilic or amphiphilic”

Court

“a matrix containing only lipophilic compounds, and as a result having an affinity for lipids and a poor affinity towards aqueous fluids”

**“outer hydrophilic matrix consisting of hydrogel forming compounds”⁸ /
“outer hydrophilic matrix consisting of hydrogels”⁹**

Cosmo

“a matrix with an affinity for water within which other matrices are incorporated”

Lupin

“a matrix containing only hydrophilic hydrogel forming compounds, and as a result having an affinity for water and a poor affinity for lipids, and not characterized as lipophilic or amphiphilic, within which other matrices are incorporated”

Court

“a matrix containing only hydrophilic hydrogel forming compounds, and as a result having an affinity for water, within which other matrices are incorporated”

Lupin seeks to supplement the Court’s previous constructions of the matrix terms in three ways: (1) as with the proposed constructions of lipophilic, amphiphilic, and hydrophilic, make clear that the terms are distinct; (2) construe the transitional phrase “consisting of;” and (3) clarify that each claimed matrix possesses certain qualities as a result of the substances that make up each respective matrix. With respect to the first point, for the reasons described above, the Court is not persuaded that its constructions need to be modified to make clear that these terms are mutually exclusive. Nor is the Court persuaded that hydrophilic must include “a poor affinity for lipids.”

⁸This term appears in claim 1 of the ’651 patent.

⁹This term appears in claim 1 of the ’799 patent.

As the parties agree, “consisting of” is a term of art with a well-established meaning. *See Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1358 (Fed. Cir. 2016). “‘Consisting of’ is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim.” *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004). There is no indication in the patents that the patentee departed from the customary meaning of “consisting of,” and the prosecution history confirms that the patentee understood and used that meaning. (*See, e.g.*, D.I. 83 Ex. 35 at 2-3) Thus, the Court agrees that Lupin’s proposed construction, consistent with the standard usage of the term, is appropriate on this point.¹⁰ Cosmo’s proposed constructions do not give any meaning to the consisting of language, as they simply define the properties of the matrices without reference to the components that make up the matrices.¹¹

Lupin’s clarification that the matrix possesses qualities *as a result* of the substances that make up that matrix is also warranted. The Court’s construction of amphiphilic matrix already addresses this point, but the Court did not have occasion to decide the issue with respect to the lipophilic and hydrophilic matrix terms. *See Cosmo*, 2016 WL 4697953, at *6 n.10. Cosmo contends that its construction makes clear that there are different matrices with different properties composed of different substances. But, as with the “consisting of” language, Cosmo’s construction does not reflect the entirety of the claim language at issue. The plain language of

¹⁰Lupin does not dispute that its construction should be understood to embrace the exceptions to the closed nature of “consisting of”: (1) components or steps that are unrelated to the invention and (2) impurities ordinarily associated with the recited materials. (*See* D.I. 102 at 9 n.6) (citing *Conoco, Inc. v. Energy & Envtl. Int’l*, 460 F.3d 1349, 1360 (Fed. Cir. 2006))

¹¹The Court previously construed “outer hydrophilic matrix” and “lipophilic matrix,” not the entire phrases at issue here. *See Cosmo*, 2016 WL 4697953, at *5-6.

these claim terms require, for example, a matrix to be lipophilic because it is composed of lipophilic compounds, not simply that the matrix is lipophilic, which Lupin's constructions better capture.¹²

Accordingly, the Court will adopt Lupin's proposed constructions as modified.

C. “macroscopically homogenous composition”¹³ / “macroscopically homogenous structure”¹⁴

Cosmo	“a composition of uniform structure throughout, as observed by the naked eye”
Lupin	“a composition of uniform structure throughout that does not include any concentric layers of excipients”
Court	“a composition of uniform structure throughout, as observed by the naked eye”

The Court previously construed “macroscopically homogenous composition,” according to the plain and ordinary meaning of the term, to mean “a composition of uniform structure throughout, as observed by the naked eye.” *Cosmo*, 2016 WL 4697953, at *4. Lupin does not argue that the Court has misapprehended the ordinary meaning. Rather, Lupin suggests that intrinsic evidence demonstrates that the term must exclude concentric layers of excipients. (*See* D.I. 92 at 16-17) (citing *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001) (finding disavowal)) The Court will not depart from its previous construction – the plain and ordinary meaning – absent a showing of lexicography or disclaimer.

¹²The Court agrees that, as Lupin concedes, it is unnecessary for the constructions to include “as a whole.” (*See* D.I. 102 at 12)

¹³This term appears in claim 1 of the ’888 patent.

¹⁴This term appears in claims 1, 12, 22, and 24-26 of the ’716 patent.

See Luminara Worldwide, LLC v. Liown Elecs. Co., 814 F.3d 1343, 1353 (Fed. Cir. 2016).

Lupin contends that the specification and prosecution history of the '888 patent compel its proposed construction. These statements do not meet the exacting standards for disclaimer or prosecution history estoppel. *See Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045 (Fed. Cir. 2016); *Hill-Rom*, 755 F.3d at 1372. In particular, the '888 patent describes the "reservoir" structures of the prior art as "not macroscopically homogeneous along all the symmetry axis of the final form." Col. 2 ll. 29-31. But the patent does not specifically refer to, or exclude, all "concentric layers of excipients." The specification's description of WO 93/00889 also does not give rise to any redefinition or disclaimer of scope, as that description similarly lacks any words of exclusion. *See* col. 2 ll. 36-45.

Nor is the Court persuaded that prosecution history estoppel applies. During prosecution, the patentee, in distinguishing prior art, commented that the "macroscopically homogenous composition is different than a core made of layers or that includes a layer." (D.I. 83 Ex. 20 at 7; *see also* Ex. 16 at 5-8; Ex. 21) The patentee repeatedly distinguished the present invention from prior art on the basis of the controlled-release mechanism, which in the prior art were semi-permeable membranes surrounding a tablet core. (*See, e.g.*, D.I. 83 Ex. 20 at 6-7, Ex. 16 at 8) But these structures were more than "concentric layers of excipients," and, in context, there is no indication that the patentee intended to exclude *all* concentric layers. (*See id.*) Accordingly, the specification and prosecution history do not clearly limit the meaning of "macroscopically homogenous" as Lupin suggests.

At most, the intrinsic evidence provides an example of a structure – a reservoir – that is not macroscopically homogenous and therefore not within the scope of the claims. But it is not

clear that the passages cited by Lupin use the term in a manner inconsistent with the term's ordinary meaning. That is, reservoir systems are not macroscopically homogenous under the Court's previous construction – they are not uniform to the naked eye *because* they contain distinct, concentric layers that can be seen. (*See also* D.I. 93 Ex. B at 26-27) Hence, these statements discussing reservoir structures do not redefine or disclaim scope that would otherwise fall within the term's ordinary meaning.

Accordingly, the Court will adopt Cosmo's proposed construction.

III. CONCLUSION

The Court construes the disputed terms as explained above. An appropriate Order follows.